

REMARKS

Claims 21-30 are in this case for consideration.

A. **Interview Summary**

Applicants would first like to thank Examiner Araj for taking the time to speak over the telephone with Applicant's undersigned attorney on May 24, 2006 about how Applicants' invention differs from the cited art. As reflected in Examiner Araj's May 30, 2006 "Interview Summary", the telephone discussion focused on the limitation in all of Applicants' pending claims of "inserting posteriorly at least two permanently articulating vertebral implants..." It was agreed that, with this limitation, Applicants' claimed invention is distinguishable from the cited prior art and Applicant has thereby overcome the current prior art rejections. Nonetheless, Examiner Araj reserved the right to engage in further search and consideration. Further, Examiner Araj requested that evidence be provided by Applicant explaining why his claimed invention is patentably distinct over the prior art anterior approaches. Such evidence is hereby submitted with this Amendment in the form of the accompanying "Declaration of William Brennan M.D., F.A.C.S."

B. **Prior Art Rejections**

1. **The Invention**

Applicant has invented a method of posterior spinal disc surgery for replacing damaged vertebral discs. In the posterior approach to spinal disc surgery, one makes the surgical incision(s) in the back of the patient. By contrast, in the anterior approach to spinal disc surgery,

one makes the surgical incision in the front of the patient, typically in the abdominal region. Unlike existing anterior spinal disc surgeries, permanently articulating vertebral implant devices are inserted using Applicant's method through one or more minimally invasive posterior incisions near the site of the damaged vertebral disc. After an incision is made in Applicant's process, a partial discectomy is posteriorly performed to remove damaged fibrocartilage disc tissue. After the discectomy, at least two permanently articulating vertebral implant devices are posteriorly inserted to replace disc tissue in a way which approximates the disc's natural flexion. To avoid damage to spinal nerve tissue and provide necessary balance, at least one vertebral implant device is inserted on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

2. The Cited Art Distinguished

Applicant's claims 21, 22, 26-28 and 30 have been rejected under 35 U.S.C. § 103(a) as being obvious over Bullivant's U.S. Patent No. 5,507,816 ("Bullivant patent") in view of Peckett's "Hartshill Horseshoe" article ("Peckett article").

The Bullivant patent discloses a "ball and socket" type vertebral implant device which can be placed, by itself, between two vertebrae to replace a damaged disc.

The Peckett article discloses a small horseshoe shaped device constructed of bone tissue or titanium which can be used to help fuse two vertebrae together. The Peckett article discusses that fusion operations can be performed using either anterior or posterior approaches.

Both the Peckett article and Bullivant patent teach away from Applicant's invention. First, as previously noted, the Peckett article pertains to methods of *fusing* two

vertebrae together. During fusion surgery, the discectomy of the damaged disc is often followed by insertion of a lattice matrix between the vertebrae, such as a bonelike horseshoe, which helps the adjacent vertebrae to grow or "fuse" together into one piece. The whole purpose of a fusion operation is thus to *prevent* the vertebrae from being able to articulate relative to one another.

As an alternative to fusion surgery, articulating devices like Bullivant's "ball and socket" implant were known in the art, but, because of their size, had to be inserted anteriorly between the vertebrae.

While a posterior approach was previously known for fusion surgery, it was thought to be unavailable for arthroplasty (i.e., the insertion of articulating implant devices). As explained in the accompanying declaration from William A. Brennan M.D., F.A.C.S., a neurosurgeon certified by the American Board of Neurological Surgery who has performed over two thousand spinal surgeries, there are numerous bones and nerves blocking easy access to damaged spinal discs for the posterior approach (Brennan Decl., ¶ 5). The bones include the spinous processes, articulated processes, transverse processes, facet joint, lamina etc. *Id.* Without cutting away these bones, there is only about 1 square centimeter of room to work on each side of the disc if the posterior approach is used. *Id.* This working area can be slightly expanded if bone is cut away, but will still be quite small. *Id.* Nonetheless, trying to expand the posterior approach working area, even slightly, runs the risk of causing permanent nerve injury. *Id.* In view of the small accessible working area using a posterior approach, it is virtually impossible to cut away the entire damaged disc from only one incision. *Id.* Instead, one generally needs to make two incisions in order to approach the damaged disc from both the left and right sides. *Id.*

While fusion devices could be made small enough to work around these posterior direction obstacles, the same was thought not to be true for articulating implant devices.

Using the anterior approach, one can gain access to the entire spinal disc through a single incision in the region of the patient's abdomen (Brennan Decl., ¶ 6). This greater access comes at a price, though. *Id.* For lumbar spinal surgeries using the anterior approach, one needs to cut through and move aside extensive muscle and intestinal tissue in order to gain access to the damaged disc. *Id.* In so doing, one runs the risk of inadvertently cutting the iliac vein and causing the patient to bleed extensively, possibly fatally. *Id.* Despite all the drawbacks of the anterior approach to disc replacement surgery, it was thought in the art of spinal surgery that the anterior approach would be the only way a device could be implanted to fully replace, both in size and function, a damaged disc (Brennan Decl., ¶ 7).

The reason Applicant's posterior approach to arthroplasty is patentability distinct from prior art anterior approaches (e.g., the Bullivant patent) is because Applicant cast aside a number of common misconceptions in the field (Brennan Decl., ¶ 8). For example, contrary to conventional wisdom, Applicant recognized in his invention that one does not need to use a single device which is approximately the same size as the damaged disc. *Id.* Instead, Applicant uses two or more smaller devices which each can be inserted through very small working areas. *Id.* According to conventional wisdom, Applicant's two or more smaller devices will not work because they inhibit axial rotation. *Id.* (compare with Bullivant patent). Again, conventional wisdom is wrong in the case of damaged discs in the lumbar region because those discs are not intended by the body to axially rotate. *Id.* Applicant observed that in the lumbar region, for example, the facet joints naturally found in the human body act as a type of doorstep to prevent

full rotational movement. In fact, in cases where disc replacement devices have been anteriorly implanted in the lumbar region to allow full axial rotation, patient complications have arisen from excessive axial rotation. *Id.*

Applicant reasoned that if full rotational movement was not necessary, articulating implant devices could be made smaller and inserted in a way which would inhibit rotational movement. Because of all the bone and nerve obstacles to such a posterior insertion, Applicant further reasoned that it would be best to insert two smaller articulating implant devices around the left and right sides, respectively, of the spinal cord/spinal nerve roots so that there would be an articulating vertebral implant device on each side of the vertical medial plane defined by the spinous process of the superior and inferior vertebrae. By implanting two articulating implant devices in this way, the implant devices could provide support for each side of the spine (i.e., both the left and right sides) and the resulting resistance to rotational movement of the two devices acting together would simulate the body's own resistance through facet joints. As such, Applicant's invention provides a less invasive, less dangerous surgery and more faithfully replaces the damaged disc, at least in the lumbar region, than either the "ball and socket" type anterior implant devices (e.g., the Bullivant patent) or the existing fusion technology (e.g., the Peckett article).

For these reasons, Applicant's invention defies the conventional wisdom that a full size disc replacement device permitting axial rotation, such as that shown in the Bullivant patent, needs to be used for disc replacement surgery and the anterior method is the only choice available to surgeons for such a disc replacement device (Brennan Decl., ¶ 9). Instead, Applicant has shown that, if two or more disc replacement devices are used which are small enough to fit

through the very small posterior working areas, these devices can be successfully placed on each side of the medial plane defined by the spinous processes and thereby make the posterior approach a practical, if not preferable, alternative to conventional anterior disc replacement surgery. *Id.*

Since the Bullivant patent and Peckett article both teach away from Applicant's invention, neither the Bullivant patent nor the Peckett article, either alone or in combination, would render any of Applicant's presently pending claims obvious.

Applicant's claim 23-25 and 29 been rejected under 35 U.S.C. § 103(a) as being unpatentably obvious over the Bullivant patent, the Peckett article and various combinations of Wong's "Paired Cylindrical Interbody Cage Fit" article ("Wong article"), Beer's U.S. Patent No. 4,458,642 ("Beer patent") and Gauchet's U.S. Patent No. 6,579,320 ("Gauchet patent").

The Wong article discloses that two cylindrical cages which can be inserted posteriorly in vertebral fusion surgery. As with the Peckett article, the purpose of the Wong cylinders is to help the vertebrae fuse together so that relative movement between the vertebrae can be prevented. Since the Wong cylinders are designed in the shape of "cages", the vertebral bone will grow through the Wong cylinders during the course of healing so that no articulating movement will be possible.

The Beer patent discloses a single articulating vertebral implant device. There is no teaching or suggestion in the Beer patent that Beer's implant device could be inserted posteriorly or that two such devices should be placed on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

The Gauchet patent discloses a single intervertebral disc prosthesis consisting of an elastomeric body held between two plates. Again there is no teaching or suggestion in the Gauchet patent of a posterior insertion method or that two such devices should be placed on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

Since neither the Bullivant patent, Peckett article, Wong article, Beer patent or the Gauchet patent, either alone or in any combination, discloses Applicant's invention of a method for posterior insertion of a pair of permanently articulating vertebral implant devices placed on each side of a vertical medial plane defined by the spinous process of the superior and inferior vertebrae, none of the cited references would render any of Applicant's presently pending claims unpatentable.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,

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